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EXAMINER	
STITZEL, DAVID PAUL	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,998	YU ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-110* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

OFFICIAL ACTION

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 2-9 are drawn to a composition comprising: a vehicle; and at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, wherein said oligosaccharide aldonic acid or related compound is not lactobionic acid, as classified in class 435, subclass 137.

II. Claims 11-19 are drawn to a method of treating cosmetic/dermatological conditions/disorders comprising topically applying a composition comprising: a vehicle; and at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, wherein said oligosaccharide aldonic acid or related compound is not lactobionic acid, as classified in class 424, subclass 401.

III. Claims 20-30 are drawn to a composition comprising: a vehicle; at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, wherein said oligosaccharide aldonic acid or related compound is not lactobionic acid; and a cosmetic, pharmaceutical, or other topical agent, as classified in class 424, subclasses 204.1, 230.1 and 231.1, as well as class 435, subclass 88.

IV. Claims 31-42 are drawn to a method of treating cosmetic/dermatological conditions/disorders comprising topically applying a composition comprising: a vehicle; at least one compound selected from the group consisting of oligosaccharide aldonic acids

and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, wherein said oligosaccharide aldonic acid or related compound is not lactobionic acid; and a cosmetic, pharmaceutical, or other topical agent, as classified in class 424, subclass 405.

V. Claims 43-56 are drawn to a composition comprising: a vehicle; at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, wherein said oligosaccharide aldonic acid or related compound is not lactobionic acid; and an inorganic alkali, an organic alkali, or amphoteric, as classified in class 423, subclass 352.

VI. Claims 57-70 are drawn to a method of treating cosmetic/dermatological conditions/disorders comprising topically applying a composition comprising: a vehicle; at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, wherein said oligosaccharide aldonic acid or related compound is not lactobionic acid; and an inorganic alkali, an organic alkali, or amphoteric, as classified in class 424, subclasses 665, 677 and 722.

VII. Claims 72-80 are drawn to a method of treating either skin wounds, or diseases/conditions of oral/vaginal mucosa comprising topically applying a composition comprising: a vehicle; and at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, as classified in class 424, subclass 434, as well as class 514, subclass 899.

VIII. Claims 81-90 are drawn to a method of treating either skin wounds, or diseases and/or conditions of oral mucosa and/or vaginal mucosa comprising topically applying a

composition comprising: a vehicle; at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$; and a cosmetic, pharmaceutical, or other topical agent, as classified in class 424, subclass 78.06, as well as class 510, subclass 130.

IX. Claims 91-104 are drawn to a method of treating either skin wounds, or diseases and/or conditions of oral mucosa and/or vaginal mucosa comprising topically applying a composition comprising: a vehicle; at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$; and an inorganic alkali, an organic alkali, or amphoteric, as classified in class 514, subclass 419.

X. Claim 108 is drawn to a method of treating cosmetic/dermatological conditions/disorders of the skin comprising topically applying a composition comprising lactobionic acid, as classified in class 514, subclasses 846, 847 and 887.

XI. Claims 106-107 are drawn to a method of treating cosmetic/dermatological conditions/disorders of the skin comprising topically applying a composition comprising: lactobionic acid; and a cosmetic, pharmaceutical, or other topical agent, as classified in class 514, subclasses 828 and 848.

XII. Claim 108 is drawn to a method of treating cosmetic conditions of the nail comprising topically applying a composition comprising lactobionic acid, as classified in class 424, subclass 61.

XIII. Claims 106-107 are drawn to a method of treating cosmetic conditions of the nail comprising topically applying a composition comprising: lactobionic acid; and a cosmetic, pharmaceutical, or other topical agent, as classified in class 510, subclass 118.

XIV. Claim 109 is drawn to a method of forming a gel matrix on the skin or mucosa comprising topically applying a composition comprising at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, as classified in class 424, subclass 78.03.

XV. Claim 109 is drawn to a method of forming a gel matrix on the hair or nail comprising topically applying a composition comprising at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, as classified in class 510, subclass 119, as well as class 514, subclass 880.

XVI. Claim 110 is drawn to an antioxidant composition comprising: a vehicle; and at least one compound selected from the group consisting of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, as classified in class 252, subclass 397.

1. Claim 1 links Inventions I, III and V. As such, claim 1 will therefore be examined herein on the merits for patentability along with the elected invention. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, namely claim 1. Likewise, upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from, or otherwise including all of the limitations of, the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claim(s) depending from, or including all of the limitations of, the allowable linking claim is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the

instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See In re Ziegler, 170 USPQ 129, 131-32 (CCPA 1971); and MPEP § 804.01.

Claim 10 links Inventions II, IV and VI. As such, claim 10 will therefore be examined herein on the merits for patentability along with the elected invention. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, namely claim 10. Likewise, upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from, or otherwise including all of the limitations of, the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claim(s) depending from, or including all of the limitations of, the allowable linking claim is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See In re Ziegler, 170 USPQ 129, 131-32 (CCPA 1971); and MPEP § 804.01.

Inventions I/III/V and II/IV/VI are related as a product and a method of using said product, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. See MPEP § 806.05(h). In the instant case, a product as claimed in Inventions I/III/V can be used by another method that is materially different from the method claimed in Inventions II/IV/VI. For example, as opposed to using said composition for treating cosmetic/dermatological conditions/disorders as claimed in Inventions II/IV/VI, said composition, as

claimed in Inventions I/III/V, may alternatively be used as an electroplating bath additive for obtaining a glassy film having uniform/excellent external appearance.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention I does not require the particulars of the subcombination as claimed Invention III because the composition of Invention I does not require the cosmetic, pharmaceutical, or other topical agent of Invention III for patentability. The subcombination of Invention III has a separate utility, such as a composition for treating herpes virus with a pharmaceutical agent, namely acyclovir.

Inventions I and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention I does not require the particulars of the subcombination as claimed Invention V because the composition of Invention I does not require the inorganic alkali, organic alkali, or amphoteric of Invention V for patentability. The subcombination of Invention V has a separate utility, such as a composition for treating depressive and manic depressive (biopolar) disorders with an alkali, namely lithium.

Inventions III and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention III does not require the particulars of the subcombination as claimed Invention V because the

composition of Invention III does not require the inorganic alkali, an organic alkali, or amphoteric of Invention V for patentability. The subcombination of Invention V has a separate utility, such as a composition for treating depressive and manic depressive (biopolar) disorders with an alkali, namely lithium.

Inventions II and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention II does not require the particulars of the subcombination as claimed Invention IV because the method of Invention II does not require the cosmetic, pharmaceutical, or other topical agent of Invention IV for patentability. The subcombination of Invention IV has a separate utility, such as a method of treating herpes virus with a pharmaceutical agent, namely acyclovir.

Inventions II and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention II does not require the particulars of the subcombination as claimed Invention VI because the composition of Invention II does not require the inorganic alkali, organic alkali, or amphoteric of Invention VI for patentability. The subcombination of Invention VI has a separate utility, such as a method of treating depressive and manic depressive (biopolar) disorders with an alkali, namely lithium.

Inventions IV and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by

itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention IV does not require the particulars of the subcombination as claimed Invention VI because the composition of Invention IV does not require the inorganic alkali, organic alkali, or amphoteric of Invention VI for patentability. The subcombination of Invention VI has a separate utility, such as a method of treating depressive and manic depressive (biopolar) disorders with an alkali, namely lithium.

Claim 71 links Inventions VII, VIII and IX. As such, claim 71 will therefore be examined herein on the merits for patentability along with the elected invention. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, namely claim 71. Likewise, upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from, or otherwise including all of the limitations of, the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claim(s) depending from, or including all of the limitations of, the allowable linking claim is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See In re Ziegler, 170 USPQ 129, 131-32 (CCPA 1971); and MPEP § 804.01.

Inventions VII and VIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention VII does not require the particulars of the subcombination as claimed Invention VIII because the method of Invention VII does not require the cosmetic, pharmaceutical, or other topical agent of

Invention VIII for patentability. The subcombination of Invention VIII has a separate utility, such as a method of treating herpes virus with a pharmaceutical agent, namely acyclovir.

Inventions VII and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention VII does not require the particulars of the subcombination as claimed Invention IX because the composition of Invention VII does not require the inorganic alkali, organic alkali, or amphoteric of Invention IX for patentability. The subcombination of Invention IX has a separate utility, such as a method of treating gingivitis with an organic alkali, namely guanidine.

Inventions VIII and IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention VIII does not require the particulars of the subcombination as claimed Invention IX because the composition of Invention VIII does not require the inorganic alkali, organic alkali, or amphoteric of Invention IX for patentability. The subcombination of Invention IX has a separate utility, such as a method of treating gingivitis with an organic alkali, namely guanidine.

Claim 105 links Inventions X and XI. As such, claim 105 will therefore be examined herein on the merits for patentability along with the elected invention. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, namely claim 105. Likewise, upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from, or otherwise including all of the limitations of, the allowable

linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claim(s) depending from, or including all of the limitations of, the allowable linking claim is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See In re Ziegler, 170 USPQ 129, 131-32 (CCPA 1971); and MPEP § 804.01.

Inventions X and XI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention X does not require the particulars of the subcombination as claimed Invention XI because the method of Invention X does not require the cosmetic, pharmaceutical, or other topical agent of Invention XI for patentability. The subcombination of Invention XI has a separate utility, such as a method of treating onychomycosis of the nail with an antifungal pharmaceutical agent, namely terbinafine.

Claim 105 links Inventions XII and XIII. As such, claim 105 will therefore be examined herein on the merits for patentability along with the elected invention. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, namely claim 105. Likewise, upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from, or otherwise including all of the limitations of, the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claim(s) depending from, or including all of the limitations of, the allowable linking claim is/are presented in a continuation or divisional application, the claims of the continuation or divisional

application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See In re Ziegler, 170 USPQ 129, 131-32 (CCPA 1971); and MPEP § 804.01.

Inventions XII and XIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in Invention XII does not require the particulars of the subcombination as claimed Invention XIII because the method of Invention XII does not require the cosmetic, pharmaceutical, or other topical agent of Invention XIII for patentability. The subcombination of Invention XIII has a separate utility, such as a method of treating acne of the skin with an antibacterial pharmaceutical agent, namely benzoyl peroxide.

Inventions XIV and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 802.01 and 806.06. In the instant case, the method claimed in Invention XIV has a function and effect of treating epidermal tissue of the skin, whereas the method claimed in Invention XV has a function and effect of treating keratinous tissue of the nail. As a result, the methods claimed in Invention XIV has a materially different function and effect from the method claimed in Invention XV, and are therefore unrelated.

Inventions I and XVI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that: (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability; and (2) the subcombination has utility by itself or in other combinations. See MPEP § 806.05(c). In the instant case, the combination as claimed in

Invention I does not require the particulars of the subcombination as claimed Invention XVI for patentability because the composition of Invention I, due to the negative proviso recited therein must not contain lactobionic acid, whereas the composition of Invention XVI may contain lactobionic acid. The subcombination of Invention XVI has a separate utility, such as a composition comprising lactobionic acid for use as an antioxidant nutritional supplement.

2. Claims 1-18, 20-28, 31-39, 43-51, 57-65, 71-79, 81-89, 91-99, 109 and 110 are generic to a plurality of disclosed patentably distinct species of oligosaccharide aldonic acids and related compounds according to the following formula: $R_1(CHOR_2)_m(CH_2)_nCOOR_3$, wherein said oligosaccharide aldonic acids or related compounds comprise: 1. aldonic acid lactones (i.e., lactobionolactone); 2. aldobionic acids (i.e., glucobionic acids, such as isolactobionic acid); 3. aldotrionic acids (i.e., glycertrionic acids); and 4. other oligosaccharide aldonic acids and related compounds (i.e., aldotetraonic acids). The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, in the event that Applicants elect either Invention I, II, III, IV, V, VI, VII, VIII, IX, XIV, XV, or XVI for prosecution on the merits, Applicants are further required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of oligosaccharide aldonic acid or related compound (i.e., a particular glucobionic acid, such as isolactobionic acid) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1-18, 20-28, 31-39, 43-51, 57-65, 71-79, 81-89, 91-99, 109 and 110 are generic. In addition to including a listing of all claims, as well as any claims subsequently added thereto, which are readable upon the elected species, Applicants should also include a

chemical structure or a molecular formula of the elected compound, if a chemical structure or a molecular formula of said compound is not already contained within the instant specification. If Applicants are unable to provide the chemical structure or the molecular formula of said compound, the CAS (Chemical Abstract Service) number assigned to said compound will suffice.

3. Claims 20, 29-31, 41, 42, 81, 106 and 107 are generic to a plurality of disclosed patentably distinct species of cosmetic, pharmaceutical, or other topical agent (i.e., an antifungal agent, such as terbinafine). The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, in the event that Applicants elect either Invention III, IV, VIII, XI, or XIII for prosecution on the merits, Applicants are further required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of cosmetic, pharmaceutical, or other topical agent (i.e., a particular antifungal agent, such as terbinafine) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 20, 29-31, 41, 42, 81, 106 and 107 are generic. In addition to including a listing of all claims, as well as any claims subsequently added thereto, which are readable upon the elected species, Applicants should also include a chemical structure or a molecular formula of the elected compound, if a chemical structure or a molecular formula of said compound is not already contained within the instant specification. If Applicants are unable to provide the chemical structure or the molecular formula of said compound, the CAS (Chemical Abstract Service) number assigned to said compound will suffice.

4. Claims 43, 52-57, 66-70, 91 and 100-104 are generic to a plurality of disclosed patentably distinct species selected from the following genera: 1. inorganic alkali (i.e., lithium); 2. organic alkali (i.e., guanidine); 3. amphoteric (i.e., tryptophan). The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, in the event that Applicants elect either Invention V, VI or IX for prosecution on the merits, Applicants are further required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species from one of the aforementioned genera (i.e., a particular amphoteric, such as tryptophan) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 43, 52-57, 66-70, 91 and 100-104 are generic. In addition to including a listing of all claims, as well as any claims subsequently added thereto, which are readable upon the elected species, Applicants should also include a chemical structure or a molecular formula of the elected compound, if a chemical structure or a molecular formula of said compound is not already contained within the instant specification. If Applicants are unable to provide the chemical structure or the molecular formula of said compound, the CAS (Chemical Abstract Service) number assigned to said compound will suffice.

5. Claims 10, 19, 31, 40, 57 and 105 are generic to a plurality of disclosed patentably distinct species of cosmetic/dermatological conditions/disorders. The disclosed cosmetic/dermatological conditions/disorders are patentably distinct, each from the other, because they possess different clinical presentations. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, in the event that Applicants elect either Invention II, IV, VI, X, XI, XII, or XIII for prosecution on the merits, Applicants are further required under 35 U.S.C.

§ 121 to elect, for search purposes only, a single disclosed patentably distinct species of a particular cosmetic/dermatological condition/disorder (i.e., dandruff) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 10, 19, 31, 40, 57 and 105 are generic. Applicants should also include a listing of all claims, in addition to any claims subsequently added thereto, which are readable upon the species that is elected consonant with this requirement.

6. Claims 71, 81 and 91 are generic to a plurality of disclosed patentably distinct species of skin wound (i.e., burn), or disease/condition of the oral/vaginal mucosa (i.e., gum disease). The disclosed skin wounds (i.e., burn) and diseases/conditions of the oral/vaginal mucosa (i.e., gum disease) are patentably distinct, each from the other, because they possess different clinical presentations. Therefore, restriction for examination purposes as indicated is proper.

Even though this requirement is traversed, in the event that Applicants elect either Invention VII, VIII or IX for prosecution on the merits, Applicants are further required under 35 U.S.C. § 121 to elect, for search purposes only, a single disclosed patentably distinct species of either a particular skin wound (i.e., burn), or a particular disease/condition of the oral/vaginal mucosa (i.e., gum disease) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 71, 81 and 91 are generic. Applicants should also include a listing of all claims, in addition to any claims subsequently added thereto, which are readable upon the species that is elected consonant with this requirement.

Conclusion to Restriction Requirement

The Examiner has required restriction between product and methods of using claims. Where Applicants elect claims directed to a product, and the product claim is subsequently found allowable,

withdrawn methods of using claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of using claims that depend from or otherwise include all the limitations of the patentable product claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of using claims will be withdrawn, and the rejoined methods of using claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of using claims may be maintained. Withdrawn methods of using claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the methods of using claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Applicants are advised that a fully responsive reply to this requirement must include an explicit identification of a single disclosed patentably distinct species of: 1. ***oligosaccharide aldonic acid or related compound*** (i.e., a particular glucobionic acid, such as isolactobionic acid); 2. ***cosmetic,***

pharmaceutical, or other topical agent (i.e., a particular antifungal agent, such as terbinafine); 3. ***either an inorganic alkali*** (i.e., lithium), ***an organic alkali*** (i.e., guanidine), ***or an amphoteric*** (i.e., tryptophan); 4. ***a particular cosmetic/dermatological condition/disorder*** (i.e., dandruff); and 5. ***either a particular skin wound*** (i.e., burn), ***or a particular disease/condition of the oral/vaginal mucosa*** (i.e., gum disease), that is elected consonant with this requirement, and a listing of all claims, including any claims subsequently added thereto, which are readable upon the elected species. An argument that a claim is allowable or that claims are not generic is considered nonresponsive unless accompanied by an explicit election of a specific species and subspecies. See 37 C.F.R. § 1.143.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species and subspecies to be obvious variants over one another or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

If claims are added after the election, Applicants must explicitly indicate which claims are readable upon the elected species. See MPEP § 809.02(a). Amendments submitted after final rejection are governed by 37 CFR 1.116, whereas amendments submitted after allowance are governed by 37 CFR 1.312.

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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